

Remarks

Claims 1-9 were pending in this application. The Office has withdrawn claims 8 and 9 as being drawn to a nonelected invention. The Office has made the restriction requirement final. Applicants reserve the right to later appeal this requirement and/or to submit future divisional applications directed to the withdrawn claimed subject matter. Thus, in compliance with the Office's requirement, the Applicants have amended the title to more clearly reflect the invention to which the claims are now directed.

The Applicants have amended claims 1-7 and added claims 10-18. Applicants provide specific support for the amendments and new claims in the following table:

Claims	Support in Specification
1, 2, 3, 4, 5, 6, 7 ("purified")	Page 11, lines 6-14.
5, 7, 10-18 (process of hybridization)	Page 12, line 3 to page 13, line 6.
2, 5, 7, 10-18 (specific region of SEQ ID NO: 1)	Page 11, lines 6-23.

No new matter has been added. With the entry of these amendments and new claims, claims 1-7 and 10-18 and are currently pending.

Claim Objections

Claims 4 and 5 have been amended to correct misspellings.

35 U.S.C. § 101

The Office rejected claims 1-4 and 6 as an invention directed to non-statutory subject matter. The Office contends that the claims as written do not sufficiently distinguish over nucleic acids as they exist naturally by not particularly pointing out any non-naturally occurring differences between the claimed products and naturally occurring products.

Applicants have amended claims 1-7 to refer to purified DNA and probes which distinguish them from naturally-occurring material. Manual of Patent Examining Procedure (MPEP § 2105).

Applicants respectfully request reconsideration of the rejection of claims 1-4 and 6 based on U.S.C. § 101.

35 U.S.C. § 112, First Paragraph

The Office rejected claims 2 and 4-7 under 35 U.S.C. § 112, first paragraph, asserting that the specification does not reasonably provide enablement for probes comprising any “part of” SEQ ID NO: 1, for methods of detecting *P. pacificensis* and/or *P. glacincola* that employ such other probes, or for methods of detecting “analog” of *P. pacificensis* and *P. glacincola* with SEQ ID NO: 2 or other probes comprising “part of” SEQ ID NO: 1. Applicants respectfully traverse.

Simply to facilitate prosecution and without acquiescence, Applicants have amended claims 2, 5 and 7 to more specifically recite the “part of the base sequence of SEQ ID NO: 1” that is “specific to *P. pacificensis* NIBH P2K6.” (Claims 4 and 6 depend on claim 2 or claim 3.) Applicants have also added new claims 10-18 to more precisely claim the purified oligonucleotide probe.

These claims are fully enabled in light of the standards set forth in *In re Wands*. In the outstanding Office Action, the Office focused on predictability as the key *Wands* factor. While it is certainly true that the predictability of the field is one of the *Wands* factors, whether or not the results of these experiments are predictable is not the issue. Indeed, one could argue that the result of virtually any experiment is going to be unpredictable. The issue is whether the full

scope of the claims can be practiced without having to resort to undue experimentation. The M.P.E.P. provides:

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether “undue experimentation” is required to make and use the invention. ‘[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance.’ *In re Coliani*, 561 F.2d 220, 224 (CCPA 1977).

MPEP § 2164.06

In the present application, these experiments are routine, particularly in light of the information provided in the specification. Thus, the DNA of SEQ ID NO.: 1 is set forth in the specification (Specification, page 11, lines 6-14); the technology to cleave the DNA into probe-size pieces is known (Specification, page 11, line 24-page 12, line 2); the collection of the bacteria and exposure of their DNA to a probe is known (Specification, page 12, lines 16-21; Example 4, page 22, line 10-page 23, line 10; and Example 5, page 24, line 24-page 25, line 26.); and the protocols of the various hybridization experiments are known (Specification, page 12, lines 3-7; Examples 4 and 5, pages 22-28).

Moreover, Example 4 (Specification, pages 22-24) provides a step-by-step description of a hybridization test comparing various oligonucleotide DNA probes, including a probe having the nucleotide sequence of SEQ ID NO: 2 (also known as “Psypac 469-487,” *see* specification, page 21, lines 7-8). The results of the process indicate that a probe that is complimentary to the base sequence of *Psychrobacter pacificensis* succeeded in the species-specific detection of *Psychrobacter pacificensis* and *Psychrobacter glacincola*. Thus, Applicants respectfully submit that it would not require undue experimentation for one of ordinary skill in the art to prepare a probe as instantly claimed because that person would be guided by the process described in Example 4 to detect *P. pacificensis* and/or *P. glacincola*.

Finally, as discussed below when addressing the Office’s rejection under 35 U.S.C. § 112, without acquiescence to the rejection or disclaimer of the deleted subject matter, Applicants have amended claims 4 and 5 to recite only *P. pacificensis* and *P. glacincola*. Thus, Applicants submit that lack of enablement for “analogs” of *P. pacificensis* and *P. glacincola* is no longer at issue.

In sum, Applicants respectfully request the Office to withdraw its enablement rejections in light of the remarks and claim amendments herein.

35 U.S.C. § 112, Second Paragraph

The Office rejects claims 4-5 under 35 U.S.C. § 112, second paragraph, as indefinite for the recitation of the limitation, “analogs thereof.” The Office states that the term “analog” is not a standard term used in the art to identify, e.g., a particular subset of bacteria as it relates to other bacteria of a genus or species. Without acquiescence to the rejection or disclaimer of the deleted subject matter, Applicants have amended claims 4-5 to recite only *P. pacificensis* and *P. glacincola*.

The Office rejects claims 5 and 7 as incomplete for omitting essential steps according to MPEP § 2172.01. The Office states that the recitation “using an oligonucleotide probe” does not indicate to one of skill in the art the manner in which a probe is to be used to achieve detection or identification. Applicants have amended claims 5 and 7 to specify the process of hybridization as the manner in which a probe is to be used. The amendments are supported by the specification at page 12, first full paragraph.

Applicants respectfully assert that, in light of the instant claims and the remarks herein, the rejections by the Office under § 112, second paragraph, should be withdrawn.

35 U.S.C. § 102

The Office rejected claims 2 and 4-6 under 35 U.S.C. § 102(b) as being anticipated by Maruyama et al. (Marine Biology 128:705-711 [1997]) (“Maruyama et al.-1:”). The Office asserts that Maruyama at al.-1 discloses the universal 16S rRNA primer, 27f (“27f primer”) and that it is an inherent property of this primer that it is a probe comprising “part of the base sequence of SEQ ID NO: 1.” Applicants respectfully traverse.

As noted above, Applicants have amended independent claims 2 and 5 (upon which claims 4 and 6 depend) to more specifically recite the “part of the base sequence of SEQ ID NO: 1” that the invention is claiming, i.e., “a region specific to the *Psychrobacter pacificensis* NIBH P2K6 strain.” Maruyama et al.-1 does not disclose a base sequence specific to the *Psychrobacter pacificensis* strain NIBH P2K6 as now expressly recited in independent claims 2 and 5. Because Maruyama et al.-1 does not teach every element of the claims, it cannot anticipate the claimed invention. *See* M.P.E.P. § 2131. Applicants respectfully request withdrawal of the § 102 rejection of claims 2 and 4-6 as anticipated by Maruyama et al.-1.

The Office rejected claims 2 and 4-6 under 35 U.S.C. § 102(b) as being anticipated by Bowman et al., as evidenced by Maruyama et al.-1. For the same reasons as for Maruyama et al.-1, the Bowman reference does not anticipate claims 2 and 4-6.

The Office rejects claims 1-7 under 35 U.S.C. § 102(a) as being clearly anticipated by Maruyama et al. (International Journal of Systemic and Evolutionary Microbiology 50:835-846 [3/2000]) (“Maruyama et al.-2”), as evidence by GenBank Accession No. ABO 16057 (5/10/2000). The Office also rejects claim 1 under 35 U.S.C. § 102(a) as being anticipated by Maruyama et al. (Applied and Environmental Microbiology 66(5):2211-2215 [5/2000; available 5/10/2000]) (“Maruyama et al.-3”), as evidenced by GenBank Accession No. ABO16057

(5/10/2000). The Office notes that these rejections may be overcome by the filing of a Katz-type declaration or by establishing priority of the invention to May 25, 1999, by filing a certified translation of priority document JP 11/145342. Applicants submit herewith a translation of priority document JP 11/145342, and a signed statement that the translation of the certified copy is accurate. In light of this submission, Applicants respectfully request that the Office withdraw the rejections based on the Maruyama et al.-2 and Maruyama et al.-3 references.

Conclusion

With the entry of the instant amendments, claims 1-7 and 10-18 are currently pending. For the reasons set forth above, the claims are in condition for allowance. If the Examiner has any comments or questions, the Applicants' representative can be reached at the following number, (650) 849-6677.

Please grant any extensions of time required to enter this amendment and response, and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 8, 2004

By: Deborah J. Acker
Deborah J. Acker
Reg. No. 48,916